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| 10/518,297 | 08/24/2005 | Jonas Angstrom | 0933-0232PUS1 | 6676 |
| 2292 7590 06/18/2009 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747 | | | | |
| EXAMINER BLAND, LAYLA D | | | | |
| ART UNIT | | PAPER NUMBER | | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary**Application No.**

10/518,297

Applicant(s)

ANGSTROM ET AL.

Examiner

LAYLA BLAND

Art Unit

1623

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 76-92, 94-104 and 106-109 is/are pending in the application.
- 4a) Of the above claim(s) 76-91 and 98-104 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 92, 94-97, 106-109 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 25, 2009 has been entered.

This Office Action is in response to Applicant's request for continued examination (RCE) filed March 25, 2009, and amendment and response to the Final Office Action (mailed September 25, 2008), filed March 25, 2009 wherein claims 92 is amended, claims 93 and 105 are canceled, and claims 107-09 are newly submitted.

Claims 76-92, 94-104, and 106-109 are pending in this application. Claims 76-91 and 98-104 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on December 5, 2007.

Claims 92, 94-97, and 106-109 are examined on the merits herein.

In view of the cancellation of claim 105, all rejections made with respect to that claim in the previous office action are withdrawn.

In view of Applicant's amendment submitted March 25, 2009, the rejection of claims 92, 94-97, 105, and 106 under 35 USC 112, first paragraph, for lacking enablement for preventing gastrointestinal infections, is withdrawn.

In view of Applicant's amendment submitted March 25, 2009, the rejection of claims 92, 94-97, 105, and 106 under 35 U.S.C. 102(b) as being anticipated by Pickering is withdrawn because the amended claims require that the composition is not human milk.

The following are new rejections:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 92, 97, and 106 are rejected under 35 U.S.C. 102(b) as being anticipated by Finke (CA 2394090, June 14, 2001).

Finke teaches an oligosaccharide composition which approximates to human milk [see abstract]. Human milk oligosaccharides support the normal intestinal flora necessary for function of the gastrointestinal tract and repress pathogenic germs [page 1, lines 26-30] and prevent the adhesion of pathogenic germs and/or substances such as bacteria, toxins, and eukaryotic parasites, the first step of an infection being thereby prevented [page 2, lines 1-9]. Isolation of oligosaccharide fractions can be done using

known separation methods [page 5, lines 21-22]. The oligosaccharide mixture can be used as prophylaxis against gastrointestinal infections or for treating of disorders caused by a faulty bacterial or viral colonization of the gastrointestinal tract [page 8, lines 1-13, and claim 8]. The oligosaccharide mixture should contain a neutral fraction and an acidic fraction [page 4, lines 25-28]. Suitable acidic oligosaccharides include 2,3'-sialyl lactose (one elected species) [page 11, Example 4] and suitable neutral oligosaccharides include lacto-N-neo-tetraose (other elected species) [page 11, Example 5]. Finke teaches administration of the claimed oligosaccharides to the claimed patient population (those in need of treatment for gastrointestinal infection). Thus, the claims are anticipated by Finke.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 94-96 and 107-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Finke (CA 2394090, June 14, 2001) in view of Zopf (Lancet Vol 347, April 13, 1996, pp. 1017-1021) or Pickering (Infection 21 (1993) No. 6, pp. 355-357, of record).

Finke teaches administration of an oligosaccharide mixture for treatment of gastrointestinal infection caused by bacterial or viral colonization of the intestinal tract, as set forth above. Finke does not teach specific pathogens or their effects.

Zopf teaches that bacteria for which oligosaccharides have been shown to be prophylactic or therapeutic *in vivo* or are effective antiadhesive agents include *Escherichia coli* and *Helicobacter pylori*, as well as *Salmonella typhimurum* and *Vibrio cholerae* [page 1017, Table]. It is noted that *Escherichia coli* and *Helicobacter pylori* are known to cause diarrhea, as mentioned in the instant specification (page 1).

Pickering teaches that human milk oligosaccharides are protective against *Campylobacter jejuni*, enteropathogenic *E. coli*, and enterotoxigenic *E. coli* [page 355, Table 1].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer Finke's composition to a subject suffering from or at risk for bacterial infections such as those taught by Zopf or Pickering. Finke teaches the treatment of bacterial gastrointestinal infections generally, and Zopf and Pickering teach particular bacteria which are known to be treatable using oligosaccharides. Thus, the skilled artisan could predict that the bacterial infections taught by Zopf or Pickering could be treated using Finke's oligosaccharide composition.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAYLA BLAND whose telephone number is (571)272-9572. The examiner can normally be reached on Monday - Friday, 7:00 - 3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anna Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Layla Bland/
Examiner, Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623